

2007N-0262 Use of Ozone-Depleting Substances; Removal of Essential-Use Designation (Epinephrine)**FDA Comment Number : EC9****Submitter :** Mr. Bela Feketekuty**Date & Time:** 11/20/2007 02:11:06**Organization :** asthma patients**Category :** Individual Consumer**Issue Areas/Comments****GENERAL**

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I had asthma since childhood. When I get an asthma attack, the only medicine that worked for me so far for many years has been Primatene Mist. Therefore, I am begging the FDA to keep the essential use status for Primatene Mist and other inhalers because serious medical problems will result when a person has an asthma attack and he/she has no medicine available to relieve the condition. I am completely and totally at a loss how the advisory panel could remove the essential use status for Primatene Mist by an 11-7 vote (a close vote) when around 3 million asthma patients use Primatene Mist. The following questions should be considered in regard to the advisory panel's close decision. Did the advisory committee study how much CFC is released by this small medical inhaler and what impact it has on the environment? Did the advisory panel call as witnesses asthma patients who use Primatene Mist when they get an asthma attack? Did the advisory panel conduct a poll among the asthma patients in order to find out why asthma patients use Primatene Mist when they get an asthma attack? How can around 3 million asthma patients be wrong?

I went to several pulmonologists who specialize in asthma. Unfortunately, all the medicine that the asthma specialists prescribed to me did NOT work and in fact some of the drugs ruined my stomach. When I asked the asthma specialists what I should do when I get an asthma attack, they did not have an answer for me. Therefore, my only remedy has been to use Primatene Mist which has always helped me.

If the FDA prohibits Primatene Mist, FDA will condemn me and many other asthma patients to suffer serious side effects because we will have no available medicine when we get an asthma attack. I am sure that FDA does not want these medical complications to occur to me and many other asthma patients because FDA had prohibited the medicine that helps us to get over an asthma attack. Furthermore, many asthma patients will have trouble sleeping at night causing other serious conditions especially when we drive to our jobs or grocery stores. Therefore, FDA must keep the 'essential use' status of Primatene Mist.

Or at least FDA should work with Wyeth, the manufacturer of Primatene Mist, (and other manufacturers) to develop an inhaler that does not contain CFC. I read on Wyeth's website that this is a possibility if FDA agrees to be reasonable and work with Wyeth. The health of the asthma patients requires nothing less.

If there are any questions, please contact me at Tel. (301) 493-9166 or 9900 Pomona Drive Bethesda, MD 20817. Thank you.

